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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,684	10/17/2001	Maria-Grazia Ascenzi	3272/1H629US2	6620

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EXAMINER	
THANGAVELU, KANDASAMY	
ART UNIT	**PAPER NUMBER**
2123	

DATE MAILED: 07/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/981,684	Applicant(s) ASCENZI, MARIA-GRAZIA	
	Examiner Kandasamy Thangavelu	Art Unit 2123	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 October 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 3 Sets

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-5 of the application have been examined.

Information Disclosure Statement

2. Acknowledgment is made of the information disclosure statements filed on February 10, 2002, March 29, 2002, April 5, 2004, April 28, 2004 and May 12, 2004 together with copies of the papers. The patents and papers have been considered in reviewing the claims.

Drawings

3. The drawings are objected to; see a copy of Form PTO-948 for an explanation.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Crolet et al.** ("Compact Bone: Numerical simulation of mechanical characteristics", J. Biomechanics, Vol. 26, No. 6, 1993) in view of **Manolagas et al.** (U.S. Patent 6,416,737).

6.1 **Crolet et al.** teaches Compact Bone: Numerical simulation of mechanical characteristics. Specifically, as per claim 1, **Crolet et al.** teaches a model of macrostructural properties of a bone, wherein the model comprises hierarchical structural and hierarchical mechanical properties of microstructure of the bone (Page 677, Abstract; Page 677, CL2, Para 1; Page 678, CL2, Para 4 to Page 682, CL2, Para 3).

Crolet et al. does not expressly teach that the model comprises interactions of the bone with external force. **Manolagas et al.** teaches that the model comprises interactions of the bone with external force (CL2, L32-36), as weak bone structure causes the bone to respond incompetently to the mechanical requirements of the skeleton (CL2, L25-29) and it would be desirable to assess how the bone will respond to the external forces. It would have been obvious

to one of ordinary skill in the art at the time of Applicant's invention to modify the model of **Crolet et al.** with the model of **Manolagas et al.** that included the model comprising interactions of the bone with external force e. The artisan would have been motivated because weak bone structure would cause the bone to respond incompetently to the mechanical requirements of the skeleton and it would be desirable to assess how the bone would respond to the external force.

7. Claims 2 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Crolet et al.** ("Compact Bone: Numerical simulation of mechanical characteristics", J. Biomechanics, Vol. 26, No. 6, 1993) in view of **Manolagas et al.** (U.S. Patent 6,416,737), and further in view of **Jiang et al.** (U.S. Patent 6,442,287).

7.1 As per claim 2, **Crolet et al.** and **Manolagas et al.** teach the model of claim 1. **Crolet et al.** teaches that the bone is compact bone (Page 677, Abstract).

Crolet et al. does not expressly teach that the bone is cancellous bone. **Jiang et al.** teaches that the bone is cancellous bone (CL1, L12-17; CL1, L63-66; CL2, L63 to CL3, L3), as analysis of trabecular (cancellous) bone mass and bone structural pattern enables assessment of bone strength and prediction of the risk of fracture (CL2, L25-29). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the model of **Crolet et al.** with the model of **Jiang et al.** that included the bone being cancellous bone. The artisan would have been motivated because analysis of trabecular (cancellous) bone mass and bone structural pattern would enable assessment of bone strength and prediction of the risk of fracture.

7.2 As per claim 4, **Crolet et al.** and **Manolagas et al.** teach the model of claim 1. **Crolet et al.** and **Manolagas et al.** also teach the method of using the model as defined in claim 1 as indicated in Paragraph 6.1 above.

Crolet et al. does not expressly teach a method of predicting deformation and fractures of bone using the model. **Jiang et al.** teaches a method of predicting deformation and fractures of bone using the model (CL1, L12-17; CL1, L63-66), as one of the functions of the bone is to resist mechanical failure such as fracture and permanent deformation (CL2, L35-36). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **Crolet et al.** with the method of **Jiang et al.** that included a method of predicting deformation and fractures of bone using the model. The artisan would have been motivated because one of the functions of the bone has been to resist mechanical failure such as fracture and permanent deformation.

8. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Crolet et al.** ("Compact Bone: Numerical simulation of mechanical characteristics", J. Biomechanics, Vol. 26, No. 6, 1993) in view of **Manolagas et al.** (U.S. Patent 6,416,737), and further in view of **Winder** (U.S. Patent 6,213,958), **Ascenzi et al.** ("The tensile properties of single osteons", August, 1965), **Ascenzi et al.** ("The shearing properties of single osteons", September, 1971), **Ascenzi et al.** ("The torsional properties of single selected osteons", October 1993), and **Ascenzi et al.** ("Pinching in longitudinal and alternate osteons during cyclic loading", November, 1996).

8.1 As per claim 2, **Crolet et al.** and **Manolagas et al.** teach the model of claim 1. **Crolet et al.** does not expressly teach that the mechanical properties are selected from the group consisting of tension, compression, shear, bending, torsion, prestress, pinching, and cement line slippage. **Winder** teaches that the mechanical properties are selected from the group consisting of compression and bending (CL2, L19-20; CL13, L57-66; CL13, L40-45), as the standard for predicting fracture risks is the accurate measurement of mechanical strength of the bone (CL2, L19-20); and the mechanical properties of the bone such as its strength and toughness depends on its architecture at the microscopic and macroscopic level (CL10, L63-67). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the model of **Crolet et al.** with the model of **Winder** that included the mechanical properties being selected from the group consisting of compression and bending. The artisan would have been motivated because the standard for predicting fracture risks would be the accurate measurement of mechanical strength of the bone; and the mechanical properties of the bone such as its strength and toughness would depend on its architecture at the microscopic and macroscopic level.

Crolet et al. does not expressly teach that the mechanical properties are selected from the group consisting of tension and prestress. **Ascenzi et al.** (August, 1965) teaches that the mechanical properties are selected from the group consisting of tension and prestress (Abstract), as the degree of calcification of the bone increases the modulus of elasticity with additional amounts of calcium compounds; the modulus of elasticity in tension corresponds to that of the collagen; in osteons having longitudinal arrangement of the bundles of fibers in successive lamellae the ultimate tensile strength and modulus of elasticity are greater than in osteons whose

bundles in successive lamellae change through an angle of about 90 degrees (Abstract, L7-13). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the model of **Crolet et al.** with the model of **Ascenzi et al.** (August, 1965) that included the mechanical properties being selected from the group consisting of tension and prestress. The artisan would have been motivated because the degree of calcification of the bone would increase the modulus of elasticity with additional amounts of calcium compounds; the modulus of elasticity in tension would correspond to that of the collagen; in osteons having longitudinal arrangement of the bundles of fibers in successive lamellae the ultimate tensile strength and modulus of elasticity would be greater than in osteons whose bundles in successive lamellae changed through an angle of about 90 degrees.

Crolet et al. does not expressly teach that the mechanical properties are selected from the group consisting of shear and prestress. **Ascenzi et al.** (September, 1971) teaches that the mechanical properties are selected from the group consisting of shear and prestress (Abstract), as the shearing strength and the modulus of elasticity of osteons increase as the calcification proceeds; the shearing strength in single osteons is markedly lower than the tensile and compressive strength for the samples of same type; and the shearing of the osteons is related to the lamellar structure (Abstract, L9-15). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the model of **Crolet et al.** with the model of **Ascenzi et al.** (September, 1971) that included the mechanical properties being selected from the group consisting of shear and prestress. The artisan would have been motivated because the shearing strength and the modulus of elasticity of osteons would increase as the calcification proceeded; the shearing strength in single osteons would be markedly lower than the tensile and

compressive strength for the samples of same type; and the shearing of the osteons would be related to the lamellar structures.

Crolet et al. does not expressly teach that the mechanical properties are selected from the group consisting of torsion and prestress. **Ascenzi et al.** (October 1993) teaches that the mechanical properties are selected from the group consisting of torsion and prestress (Abstract; Page 880, Fig. 4; Page 881, CL1, Para 4), as the longitudinal osteons indicate most resistance to torsional loading; and the transverse osteons have low resistance to torsional loading (Abstract, L8-10). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the model of **Crolet et al.** with the model of **Ascenzi et al.** (October 1993) that included the mechanical properties being selected from the group consisting of torsion and prestress. The artisan would have been motivated because the longitudinal osteons would indicate most resistance to torsional loading; and the transverse osteons would have low resistance to torsional loading ructures.

Crolet et al. does not expressly teach that the mechanical properties are selected from the group consisting of pinching and prestress. **Ascenzi et al.** (November, 1996) teaches that the mechanical properties are selected from the group consisting of pinching and prestress (Abstract), as pinching occurs in longitudinal osteons consisting of longitudinal fibrils, especially in incompletely calcified ones; in alternate osteons, protected by lamellae containing transversely oriented fibrils, pinching are reduced (Abstract, L10-13). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the model of **Crolet et al.** with the model of **Ascenzi et al.** (November, 1996) that included the mechanical properties being selected from the group consisting of pinching and prestress. The artisan would have been

motivated because pinching would occur in longitudinal osteons consisting of longitudinal fibrils, especially in incompletely calcified ones; in alternate osteons, protected by lamellae containing transversely oriented fibrils, pinching would be reduced.

Crolet et al. does not expressly teach that the mechanical properties are selected from the group consisting of prestress and cement line slippage. **Ascenzi et al.** (September, 1971) teaches that the mechanical properties are selected from the group consisting of prestress and cement line slippage (Abstract), as the resistance to shearing of the cementing substance at the boundaries of the osteons may be greater than the resistance of the osteon itself (Abstract, L17-19). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the model of **Crolet et al.** with the model of **Ascenzi et al.** (September, 1971) that included the mechanical properties being selected from the group consisting of prestress and cement line slippage. The artisan would have been motivated because the resistance to shearing of the cementing substance at the boundaries of the osteons might be greater than the resistance of the osteon itself.

9. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Crolet et al.** ("Compact Bone: Numerical simulation of mechanical characteristics", J. Biomechanics, Vol. 26, No. 6, 1993) in view of **Manolagas et al.** (U.S. Patent 6,416,737), and further in view of **Copland III et al.** (U.S. Patent 6,333,313) and **Agrawal et al.** (U.S. Patent 5,947,893).

9.1 As per claim 5, **Crolet et al.** and **Manolagas et al.** teach the model of claim 1. **Crolet et al.** and **Manolagas et al.** teach the method of using the model as described in Paragraph 6.1 above.

Crolet et al. does not expressly teach a method of identifying the requirements of bone reconstruction. **Copland III et al.** teaches a method of identifying the requirements of bone reconstruction (CL8, L9-13), as bone reconstruction requires ability to reconstruct defects in bone tissue resulting from various causes (CL8, L10-13). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **Crolet et al.** with the method of **Copland III et al.** that included a method of identifying the requirements of bone reconstruction. The artisan would have been motivated because bone reconstruction requires ability to reconstruct defects in bone tissue resulting from various causes.

Crolet et al. does not expressly teach a method of identifying the requirements of prosthesis. **Agrawal et al.** teaches a method of identifying the requirements of prosthesis (Abstract, L1-16), as long term stability of the prosthesis requires bone to form an interlock by growing into the prosthesis at the mating surface (CL1, L43-46). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **Crolet et al.** with the method of **Agrawal et al.** that included a method of identifying the requirements of prosthesis. The artisan would have been motivated because long term stability of the prosthesis would require bone to form an interlock by growing into the prosthesis at the mating surface.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Kandasamy Thangavelu whose telephone number is 703-305-0043. The examiner can normally be reached on Monday through Friday from 8:00 AM to 5:30 PM.

If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Teska, can be reached on (703) 305-9704. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-9600.

K. Thangavelu
Art Unit 2123
July 8, 2004

KEVIN J. TESKA
SUPERVISORY
PATENT EXAMINER